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| 09/899,432 | 07/06/2001 | Robert Kleiman | FLORA. 1100 | 3374 |

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| EXAMINER | |
|---|---|
| KANTAMNENI, SHOBHA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/899,432 | KLEIMAN ET AL. | |
| | Examiner | Art Unit | |
| | Shobha Kantamneni | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *91-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *91-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The amendment received on 11/05/2007, wherein claims 91, 93, 95, 97, 99, 101 have been amended.

Currently, claims 91-102 are pending.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 91-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392), in view of Sintov et al. (WO 9602244 A1), and further in view of ARQUETTE et al. (WO 9920224).

Katz et al. (5,952,392) discloses that long chain fatty acids broadly including oleic acid (C18, one double bond, see col.2 lines 12-15; col. 3, lines 5-8, col.4, lines 26-28; col.6, lines 28-35) or monounsaturated long chain alcohols broadly (e.g., C18-C28, or octadecenol, docosenol, brassidyl alcohol) in their effective amounts with a physiologically compatible carrier (e.g., cream or ointment applied to skin, or aqueous solution, see col. 12, EXAMPLE 5; Examples 12, 14-15, col.20 lines 34-35, and col.22

lines 39-40 and 64) are useful in a pharmaceutical composition for topical application, intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity. See abstract, col.1 lines 10-15 and 20-47; col.3 lines 18-21; col.7, lines 62-67; col. 12, EXAMPLE 5; Examples 14-15 at col.22-23. It is further disclosed that compositions therein for use in treating viral infections comprise active ingredient or combination of compounds as the active ingredients selected from a group consisting of saturated aliphatic alcohols, mono-unsaturated aliphatic alcohols, mono-unsaturated aliphatic amides and aliphatic acids having a carbon chain length of 18-28 carbons, wherein the active ingredient is present in an amount of 0.1 to about 50 % by weight of the final composition. See column 6, lines 28-36, lines 50-55. It is taught that the compositions therein are administered to the skin or a mucous membrane topically, parenterally or by transmembranal penetration using a cream, lotion, gel, ointment, suspension, aerosol spray or semi-solid formulation (e.g., a suppository). See column 7, lines 62-67; column 24, claims 7-11.

The prior art does not expressly disclose the employment of monounsaturated long chain alcohols in combination with the particular long chain fatty acids salts such as C20 acids, and fatty acid esters herein in a composition for treating virus-induced and inflammatory disease of skin and membranes.

Sintov et al. discloses topical pharmaceutical composition for the treatment of viral infections comprising salts of carboxylic acid which include alkali metal oleates,

C18 acid salts. See abstract; page 2, bottom paragraph; pages 3, lines 1-3, paragraph 5; page 7, EXAMPLE 1.

Arquette et al. (WO 9920224) discloses a pharmaceutical composition comprising the instant fatty alcohols at least 10% by weight (see particularly abstract and page 3 lines 15-22), and the instant fatty acid esters in their various percentages (see pages 4-8) with a physiologically compatible carrier for topical applications (see abstract and claims 1-12, especially claim 23). It is also taught that fatty acids such as oleic acid, myristic acid etc are used as emollients. See page 1, lines 24-29.

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the instant particular fatty acids salts such as C20 acid salts to treat viral infections in the methods of Katz et al. because Katz et al. (5,952,392), and Sintov et al., teach the use of C18 acids and salts (sodium salt of oleic acid) in the method of treating viral infections. One of ordinary skill in the art at the time of invention would have been motivated to utilize the fatty acid salts as instantly claimed because of an expectation of success similar to that taught for structurally similar prior art species i.e C18 acids, and salts, since structurally similar compounds usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214, and If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species, In fact, similar properties may normally be presumed when compounds are very close in structure. Moreover, fatty acid and salts of fatty acids of Katz et al. (5,952,392), Sintov

et al., and the instant particular fatty acid salts are homologs, and thus they possess same or substantially similar activities. Absent a showing of unexpected results, homologous compounds are considered to be obvious. In re Hass, 141 F.2d 127, 60 USPQ 548 (CCPA 1944), In re Henze, 85 USPQ 261 (CCPA 1950).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant long chain fatty acid salt in combination with long chain alcohols taught by Katz et al., in the method of treating virus-induced and inflammatory disease of skin and membranes.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant long chain fatty acid salt in combination with long chain alcohols because 1) the instant long chain fatty acid salt is a homolog of alkali metal oleate, and will possess similar anti-viral properties as that of alkali metal oleate, and 2) monounsaturated long chain alcohols are known to be useful to treat virus-induced and inflammatory disease of skin and membranes according to Katz et al. (5,952,392), and Sintov et al. Accordingly, one of ordinary skill in the art would have been motivated to combine long chain fatty acid salt and long chain alcohol with reasonable expectation success of obtaining a pharmaceutical composition for treating virus-induced and inflammatory disease of skin and membranes

It would have been obvious to a person of ordinary skill in the art at the time of invention to add instantly claimed fatty acid esters to the composition comprising monounsaturated long chain alcohols, and alkali metal salt of fatty acid because Arquette et al. teaches that the instantly claimed fatty acid esters are known to be used

as emollients in pharmaceutical compositions. Thus, one of ordinary skill in the art at the time of invention would have been motivated to add the instantly claimed fatty acid esters taught by Arquette et al. to the composition comprising monounsaturated long chain alcohols, and salt of fatty acid with reasonable expectation of obtaining a pharmaceutical composition for treating virus-induced and inflammatory disease of skin and membranes since salts of long chain fatty acids broadly or monounsaturated long chain alcohols broadly in their effective amounts with a physiologically compatible carrier are known to be useful in pharmaceutical compositions for topical application and intramuscular and intravenous injections, for methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes.

Therefore, one of ordinary skill in the art would have reasonably expected that combining the instant fatty acid esters taught by Arquette et al. with the monounsaturated fatty alcohols, and the salts of fatty acid in a pharmaceutical composition would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes because 1) fatty acid esters are known to be used as an emollients in pharmaceutical composition comprising monounsaturated long chain alcohols, and 2) further according to Arquette emollients have beneficial effects such as softening, smoothening skin, reduce skin roughness, cracking and irritation of skin. Thus, one of ordinary skill in the art would have been reasonably expected that the combination of the instant fatty acid esters taught by Arquette et al. with the instant fatty alcohols, and the salts of oleic acid i.e instant salts of fatty acids in

a pharmaceutical composition would have at least additive therapeutic effects, and also provide additional benefits such as softening, smoothening of skin.

Claims 93-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392), in view of Sintov et al., and further in view of ARQUETTE et al. (WO 9920224) as applied to claims 91-92 above, and further in view of Katz (4,874,794) or Katz (5,070,107).

Katz et al., Sintov et al., and ARQUETTE et al. are as discussed above.

Katz et al. (5,952,392) does not explicitly teach the effective amount of monounsaturated alcohol as from about 0.1 mg to about 2 gm per 50 kg of body weight.

Katz et al. (4,874,794) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C20-C26) with a physiologically compatible carrier in a pharmaceutical composition for topical application for methods of treating viral infections and skin inflammations are 0.1 to 25 percent by weight. See abstract, col.3 lines 63-68, claims 1-2.

Katz et al. (5,070,107) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular and intravenous injections for methods of treating viral infections and skin inflammations are 0.1 mg to 2 g/per 50kg of body weight. See abstract, col.3 lines 63-68, claims 1-2.

One of ordinary skill in the art would have been motivated to optimize the effective amounts of instantly claimed long chain monounsaturated alcohols in the composition because Katz et al. '794, and '107 teaches effective amounts of structurally

similar long chain fatty alcohols active agents for treating viral infections and skin inflammations as 0.1 mg to 2 g/per 50kg of body weight. Further, it has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

***Response to Arguments***

Applicant's arguments with respect to rejection of claims 91-102 have been considered but are moot in view of the new ground(s) of rejection, and as found below.

Applicant argues that "Sintov et al. does not teach or suggest the salts of fatty acids in claim 91 as amended. Rather, Sintov et al. teaches away from the present invention by suggesting that salts of fatty acids with chain lengths of 18 or fewer carbons are preferred." These arguments have been considered, but not found persuasive. Sintov et al. broadly teaches that salts of carboxylic acids are employed in the compositions therein for the treatment of viral infections, and further teaches water-solubilized C16-C18 carboxylic acid salt, such as akali oleate as preferred. Thus even though Sintov et al. does not exemplify other salts of long chain carboxylic acids, it has been well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681

F.2d 792, 794, 215 USPQ, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983).

The 37 C.F.R. § 1.132 Affidavits by Robert Kleiman and David Ashley have been considered, but not found persuasive. The declaration does not provide any information with respect to which unsaturated long chain alcohol, fatty acid salt, and ester are employed in the combination K100, Exhibit 1, and the amounts of individual components employed in the combination K100. Further, there is no data provided for the individual fatty acid salts, and esters. The declaration merely provides antiviral activity data for n-docosanol alone, and does not provide antiviral activity data for the individual fatty acid salts, and esters. Accordingly, the data is not convincing with respect to the synergistic effects of the combination of the present invention.

Thus, the evidence presented in the declaration, and instant specification herein demonstrate that the composition comprising unsaturated fatty alcohols herein has anti-viral effects, as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c).

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Tuesday-Thursday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER